



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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Version 2021

Introduction Type:

New Item

☒ Final Version

Date:

10/2/2025

PRODUCT INFORMATION

Company Name:

Novadoz Pharmaceuticals, LLC

Application:

ANDA

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):

213483

Medical Device Class, if applicable:

DUNS:

08-110-9687

Proprietary Name (If Applicable) and Established Name:

Ivabradine Tablets 5 mg, 60

Selling Unit NDC:

72205-336-60

Unit of Use NDC:

UPC:

372205336605

UDI:

CVX Code:

MX Code:

Description:

Orange Colored, Capsule shaped, film coated tablets scored with debossing "M" & "I" on one side and "2" on other side.

Active Ingredient(s):

Ivabradine

URL for Additional Product Information:

Address:

20 Duke Road

City:

Piscataway

Key Contact:

Phone Number:

908-360-1500

Product Therapeutic Classification:

Address 2:

Suite A

State:

NJ

Zip:

08854

Email:

sales@novadozpharma.com

Fax:

732-902-2113

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range

Controlled Room – between 20 and 25 C (68° – 77° F)

Other Temperature Range Requirement

(write in)

Notes

Is this product to be shipped to customers on ice?

No

Is this product to be shipped to customers on dry ice?

No

b. Contact for temperature excursion questions:

Name:

Number:

Group E-mail:

c. Special regulations for product in any states?

Special returns requirements for this product?

d. Store product (unit of sale) upright?

No

Protect product (unit of sale) from light?

e. Shelf life:

Initial shelf life at launch (if different):

24

Months

24

Months

ADDITIONAL PRODUCT INFORMATION

The product is?

a legend device?

No

if yes, enter class #

a product kit?

No

if yes, list NDCs of component parts reverse numbered?

co-licensed?

No

latex-free?

Yes

preservative-free?

Yes

correctional institution block?

No

opioid?

No

Cannabinoid?

No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

72205-336-60

Is the Product...

Direct-Ship Only

Is the Product...

Neither

Orphan Drug Status

FDA Approval Status

Allergens Present

Country of Origin

Is this product covered under the Trade Agreements Act (TAA)?

No

PRODUCT DESCRIPTION INFORMATION

Size:

60

Strength:

5 mg

Dosage Form:

Tablets

Product Shape:

Capsule Shaped

Product Color:

Orange Colored

Product Imprint:

debossing "M" & "I" on one side and "2" on other

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:

AB

II. Generic Equivalent to What Brand?:

Corlanor

☐ Authorized Generic

*If Authorized Generic, other section fields are not applicable

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?

Yes

Is product exempt from DSCSA?

No

If yes, select exemption:

Other exemption - Write in:

Is product repackaged?

No

Is product sold by manufacturer's exclusive distributor?

No

Has FDA granted waiver/exception/exemption for product?

No

If yes, attach documentation from FDA.

GLN:

8904159670843

GCP:

89041596

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure

Yes

Item/Each

NA

Box/Carton/Bundle/Inner Pack

Yes

Case

Yes

Pallet

Saleable Quantity

1

Bottle of 60 Tablets

NA

120

Bottles in Case

4800

Bottles in Pallet

HIBCC

GTIN-14

00372205336605

NA

30372205336606

50372205336600

Unit of Use GTIN-14

00372205336605

ORDER INFORMATION

Unit of Sale

☒ Bottle

☐ Box/Carton

☐ Ampule

☐ Glass

☐ Tube

☐ Vial Liquid Sgl

☐ Vial Liquid Multi

☐ Vial Powder Sql

☐ Vial Power Multi

☐ Other: Write In

What is the NDC selling unit?

1 bottle fo 60 tablets

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

Yes

If Yes, how many of which package type?

120

Each

Inner/Carton/Pack

Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

☒ Each

☐ Gram

☐ Milliliter

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.085	NA	1.531	3.28	49.00	1
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	NA	NA
Case:	12.53	16.34	10.43	8.46	1441.81	120
Pallet:	540.85	47.24	39.37	39.76	73947.19	4,800

COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

10/2/2025

Vendor #:

Whsl. Code #:

Fineline Code:

\$75.00



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic? ☐ No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
Is the product a CA Prop 65 carcinogen? ☐ No
Is the product a CA Prop 65 reproductive toxicant? ☐ No
Does the product label bear a CA Prop 65 warning? ☐ No

- c. Contact Hazard? ☐ No
- d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.) ☐ No
- e. Does the product contain DEHP? ☐ No

Is this product regulated for shipment by DOT?
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? ☐ No

Is this product regulated for shipment by IATA?
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? ☐ No

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity? ☐ No

RQ Threshold:

Is this a marine pollutant? ☐ No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- ☐ No (if yes, identify method below)
- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? ☐ No Controlled Substance Code
- Controlled by State(s)? ☐ No Listed Chemical (List I or II) ☐ No
- ARCOS Reportable? ☐ No If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: ☐ No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

☐ Yes

Restricted to retail pharmacy only:

☐ No

Restricted to hospital, clinics, and physician offices only:

☐ No

Restricted from US territories? (explain in comments)

☐ No

Comments:

SDS Hazard Classification

- ☐ Organic ☐ Corrosive
- ☐ Inorganic ☐ Oxidizer
- ☐ Steroid/Androgen ☐ Contact Hazard

Does the product have an Aerosol class? If yes,
identify NFPA Storage Level:

☐ No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?
If yes, indicate which:

☐ No

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? ☐ No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required ☐ No

Limited Distribution Requirement ☐ No

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively: ☐

Wholesale distributor support: ☐

Provider Name:

Site Enrollment Number assigned
by Supplier:

☐ No

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

Registry:

Registry Program Contact Name:

☐ No

Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: ☐

URL/Link to returns policy:

Special regulations or returns requirements for this
product in certain states? ☐ No

If so, which states? Other requirements? Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
<p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<p>Miscellaneous Notes:</p> <p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>